

**TENT COOPERATION TREATY**

**PCT**

**INTERNATIONAL SEARCH REPORT**

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference <b>RS/mg g67827</b>	<b>FOR FURTHER ACTION</b> see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. <b>PCT/EP 99/ 05137</b>	International filing date (day/month/year) <b>19/07/1999</b>	(Earliest) Priority Date (day/month/year) <b>30/07/1998</b>
Applicant  <b>BIOSEARCH ITALIA S.P.A. et al.</b>		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

**1. Basis of the report**

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☐ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

☐ the text is approved as submitted by the applicant.

☒ the text has been established by this Authority to read as follows:

**NEW INJECTABLE FORMULATIONS CONTAINING RAMOPLANIN**

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

☐ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

☒ None of the figures.

## INTERNATIONAL SEARCH REPORT

International Application No

EP 99/05137

**A. CLASSIFICATION OF SUBJECT MATTER**  
 IPC 7 A61K9/08 A61K9/107

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 95 21636 A (GRUPPO LEPETIT S.P.A., IT) 17 August 1995 (1995-08-17) the whole document ---	1-19
A	EP 0 318 680 A (GRUPPO LEPETIT SP.A., IT) 7 June 1989 (1989-06-07) claims 1,15-20 page 7, line 2 - line 15 ---	1-19
A	EP 0 321 696 A (GRUPPO LEPETIT S.P.A., IT) 28 June 1989 (1989-06-28) cited in the application claims 1,11-15 page 6, line 38 - line 51 --- -/--	1-19

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

1 November 1999

Date of mailing of the international search report

05/11/1999

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
 NL - 2280 HV Rijswijk  
 Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
 Fax: (+31-70) 340-3016

Authorized officer

Scarponi, U

# INTERNATIONAL SEARCH REPORT

International Application No  
EP 99/05137

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 337 203 A (GRUPPO LEPETIT S.P.A., IT) 18 October 1989 (1989-10-18) cited in the application claims 1,13-18 page 7, line 44 - line 55 -----	1-19
A	GB 2 045 231 A (GRUPPO LEPETIT S.P.A., IT) 29 October 1980 (1980-10-29) cited in the application claims 1,5 page 5, line 23 - line 38 -----	1-19

## INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

/EP 99/05137

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9521636	A	17-08-1995	AU 681761 B	04-09-1997
			AU 1663695 A	29-08-1995
			CA 2181819 A	17-08-1995
			EP 0744971 A	04-12-1996
			HU 74669 A	28-01-1997
			JP 10501428 T	10-02-1998
			US 5752941 A	19-05-1998
			ZA 9501132 A	17-10-1995
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EP 318680	A	07-06-1989	AT 100470 T	15-02-1994
			DE 3887292 D	03-03-1994
			DE 3887292 T	05-05-1994
			DK 612188 A	28-05-1989
			ES 2061590 T	16-12-1994
			JP 1168700 A	04-07-1989
			JP 2055157 C	23-05-1996
			JP 7091315 B	04-10-1995
-----				
EP 321696	A	28-06-1989	AT 99329 T	15-01-1994
			CA 1338848 A	14-01-1997
			DE 3886718 D	10-02-1994
			DE 3886718 T	28-04-1994
			DK 690288 A	24-06-1989
			ES 2061610 T	16-12-1994
			JP 1211600 A	24-08-1989
			JP 2507573 B	12-06-1996
			US 5108988 A	28-04-1992
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EP 337203	A	18-10-1989	AT 118017 T	15-02-1995
			CA 1337838 A	26-12-1995
			DE 68920898 D	16-03-1995
			DE 68920898 T	24-05-1995
			DK 170189 A	14-10-1989
			ES 2067493 T	01-04-1995
			JP 2028196 A	30-01-1990
			JP 2647490 B	27-08-1997
			US 5491128 A	13-02-1996
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GB 2045231	A	29-10-1980	AR 222217 A	30-04-1981
			AT 370130 B	10-03-1983
			AT 187480 A	15-07-1982
			AU 533951 B	22-12-1983
			AU 5703680 A	09-10-1980
			AU 535727 B	05-04-1984
			BE 882632 A	03-10-1980
			CA 1142866 A	15-03-1983
			CH 655515 B	30-04-1986
			DE 3013246 A	16-10-1980
			DK 140080 A,B,	08-10-1980
			ES 490236 A	16-02-1981
			FI 800881 A,B,	08-10-1980
			FR 2452931 A	31-10-1980
			GR 67279 A	26-06-1981
			HK 23584 A	23-03-1984
			IE 49327 B	18-09-1985
			IL 59704 A	30-11-1983
			IT 1212411 B	22-11-1989
			JP 1446746 C	30-06-1988

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

/EP 99/05137

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
GB 2045231 A		JP 56097237 A	05-08-1981
		JP 62051274 B	29-10-1987
		JP 1478066 C	27-01-1989
		JP 62282579 A	08-12-1987
		JP 63020514 B	27-04-1988
		LU 82327 A	02-12-1981
		MX 9203210 A	01-07-1992
		NL 8001982 A,B,	09-10-1980
		NZ 193357 A	07-12-1982
		PH 17230 A	03-07-1984
		PT 71064 A	01-05-1980
		SE 441188 B	16-09-1985
		SE 8002601 A	01-12-1980
		SG 22687 G	07-07-1989
		US 4303646 A	01-12-1981
		US 4328316 A	04-05-1982
		YU 93580 A	30-06-1983
		ZA 8001629 A	25-03-1981

**PCT**

**INTERNATIONAL PRELIMINARY EXAMINATION REPORT**

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>RS/mg G67827</b>	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. <b>PCT/EP99/05137</b>	International filing date (day/month/year) <b>19/07/1999</b>	Priority date (day/month/year) <b>30/07/1998</b>
International Patent Classification (IPC) or national classification and IPC <b>A61K9/08</b>		
Applicant <b>BIOSEARCH ITALIA S.P.A. et al.</b>		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 5 sheets, including this cover sheet.

- ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand  <b>20/12/1999</b>	Date of completion of this report  <b>10.04.2000</b>
Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer  <b>Adechy, M</b>  Telephone No. +49 89 2399 8576  

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/EP99/05137

**I. Basis of the report**

1. This report has been drawn on the basis of *(substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.)*:

**Description, pages:**

1-24 as originally filed

**Claims, No.:**

1-19 as originally filed

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages:  
☐ the claims, Nos.:  
☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Yes: Claims 1-19
	No: Claims
Inventive step (IS)	Yes: Claims 1-19
	No: Claims
Industrial applicability (IA)	Yes: Claims
	No: Claims

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/EP99/05137

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2. Citations and explanations

**see separate sheet**

**VII. Certain defects in the international application**

The following defects in the form or contents of the international application have been noted:

**see separate sheet**



**Re Item V**

**Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1) Reference is made to the following documents:**

- D1: WO 95 21636 A (GRUPPO LEPETIT S.P.A.,IT) 17 August 1995 (1995-08-17)
- D2: EP-A-0 318 680 (GRUPPO LEPETIT S.P.A.,IT) 7 June 1989 (1989-06-07)
- D3: EP-A-0 321 696 (GRUPPO LEPETIT S.P.A.,IT) 28 June 1989 (1989-06-28)
- D4: EP-A-0 337 203 (GRUPPO LEPETIT S.P.A.,IT) 18 October 1989 (1989-10-18)
- D5: GB-A-2 045 231 (GRUPPO LEPETIT S.P.A.,IT) 29 October 1980 (1980-10-29)

**2) Novelty Art. 33 (1) and (2) PCT:**

The subject matter of Claim 1 discloses a pharmaceutical formulation for intravenous administration comprising ramoplanin (or a compound from the family of such an active antibiotic agent) in combination with a fat emulsion product. The combination of technical features is not disclosed in the prior art documents, therefore the subject matter of claim 1 is considered as novel. The same applies to the subject matter of the dependent Claims 2 to 17.

The subject matter of Claim 18 is view as novel, as it also refers to Claim 1-17 and the technical features of such a claim are not disclosed in the prior art documents. The same applies to the dependent Claim 19.

**3) Inventive step Art. 33 (1) and (3) PCT:**

The subject matter of Claims 1 to 19 is regarded as involving inventive step, because it is clear from the description (p. 5 lines 5-15) that the intravenous administration of the claimed antibiotic causes problems (e.g. haemolysis), when used as such; and the addition of an emulsion to this antibiotic is given as a solution to this technical problem. None of the prior art document suggests such a

solution to solve the above technical problem.

#### **4) Industrial applicability**

For the assessment of the present claims 1-19 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

#### **Re Item VII**

##### **Certain defects in the international application**

The term incorporated by reference (e. g. on p. 1 line 26, p. 6 line 6-7) should be avoided under Rule 9.1 PCT.

## PATENT COOPERATION TREATY

RIC. 1 2 APR. 2000

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

SGARBI, Renato et al.  
ING. A. GIAMBROCONO & C. S.R.L.  
Via Rosolino Pilo, 19/B  
I-20129 Milan  
ITALIE

PCT

NOTIFICATION OF TRANSMITTAL OF  
THE INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT  
(PCT Rule 71.1)

Date of mailing  
(day month year) 10.04.2000

Applicant's or agent's file reference  
RS/mg G67827

## IMPORTANT NOTIFICATION

International application No.  
PCT/EP99/05137

International filing date (day month year)  
19/07/1999

Priority date (day month year)  
30/07/1998

Applicant  
BIOSEARCH ITALIA S.P.A. et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

## 4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/



European Patent Office  
D-80298 Munich  
Tel. +49 89 2399 - 0 Tx: 523656 epmu d  
Fax: +49 89 2399 - 4465

Authorized officer

Bleeker, M

Tel. +49 89 2399-8141



# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference RS/mg G67827		FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP99/05137	International filing date (day:month:year) 19/07/1999	Priority date (day:month:year) 30/07/1998	
International Patent Classification (IPC) or national classification and IPC A61K9/08			
Applicant BIOSEARCH ITALIA S.P.A. et al.			

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.


2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand  20/12/1999	Date of completion of this report  10.04.2000
Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer  Adechy, M  Telephone No. +49 89 2399 8576



**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/EP99/05137

**I. Basis of the report**

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

**Description, pages:**

1-24 as originally filed

**Claims, No.:**

1-19 as originally filed

2. The amendments have resulted in the cancellation of:

- ☐ the description. pages:  
☐ the claims. Nos.:  
☐ the drawings. sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Yes:	Claims	1-19
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-19
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	
	No:	Claims	

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/EP99/05137

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2. Citations and explanations

**see separate sheet**

**VII. Certain defects in the international application**

The following defects in the form or contents of the international application have been noted:

**see separate sheet**

**Re Item V**

**Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1) Reference is made to the following documents:**

- D1: WO 95 21636 A (GRUPPO LEPETIT S.P.A.,IT) 17 August 1995 (1995-08-17)
- D2: EP-A-0 318 680 (GRUPPO LEPETIT S.P.A.,IT) 7 June 1989 (1989-06-07)
- D3: EP-A-0 321 696 (GRUPPO LEPETIT S.P.A.,IT) 28 June 1989 (1989-06-28)
- D4: EP-A-0 337 203 (GRUPPO LEPETIT S.P.A.,IT) 18 October 1989 (1989-10-18)
- D5: GB-A-2 045 231 (GRUPPO LEPETIT S.P.A.,IT) 29 October 1980 (1980-10-29)

**2) Novelty Art. 33 (1) and (2) PCT:**

The subject matter of Claim 1 discloses a pharmaceutical formulation for intravenous administration comprising ramoplanin (or a compound from the family of such an active antibiotic agent) in combination with a fat emulsion product. The combination of technical features is not disclosed in the prior art documents, therefore the subject matter of claim 1 is considered as novel. The same applies to the subject matter of the dependent Claims 2 to 17.

The subject matter of Claim 18 is view as novel, as it also refers to Claim 1-17 and the technical features of such a claim are not disclosed in the prior art documents. The same applies to the dependent Claim 19.

**3) Inventive step Art. 33 (1) and (3) PCT:**

The subject matter of Claims 1 to 19 is regarded as involving inventive step, because it is clear from the description (p. 5 lines 5-15) that the intravenous administration of the claimed antibiotic causes problems (e.g. haemolysis), when used as such; and the addition of an emulsion to this antibiotic is given as a solution to this technical problem. None of the prior art document suggests

solution to solve the above technical problem.

#### **4) Industrial applicability**

For the assessment of the present claims 1-19 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The E<sup>+</sup> for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

#### **Re Item VII**

##### **Certain defects in the international application**

The term incorporated by reference (e. g. on p. 1 line 26, p. 6 line 6-7) should be avoided under Rule 9.1 PCT.



# PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

## PCT

NOTIFICATION OF TRANSMITTAL OF  
THE INTERNATIONAL SEARCH REPORT  
OR THE DECLARATION

(PCT Rule 44.1)

To:

ING. A. GIAMBROCONO & C. S.R.L.  
Attn. SGARBI, Renato  
Via Rosolino Pilo, 19/b  
20129 Milano  
ITALY

Date of mailing  
(day/month/year)

05/11/1999

Applicant's or agent's file reference

RS/mg g67827

**FOR FURTHER ACTION**

See paragraphs 1 and 4 below

International application No.

PCT/EP 99/ 05137

International filing date  
(day/month/year)

19/07/1999

Applicant

BIOSEARCH ITALIA S.P.A. et al.

1. ☒ The applicant is hereby notified that the International Search Report has been established and is transmitted herewith.

**Filing of amendments and statement under Article 19:**

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

**When?** The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.

**Where?** Directly to the International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland  
Fascimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no International Search Report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Further action(s):** The applicant is reminded of the following:

Shortly after 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

Within 19 months from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within 20 months from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the International Searching Authority



European Patent Office, P.B. 5818 Patentlaan 2  
NL-2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Barbara Klaver

## NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions respectively.

### INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

#### What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

#### When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

#### Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

#### How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

#### What documents must/may accompany the amendments?

##### Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

## NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:  
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
2. [Where originally there were 15 claims and after amendment of all claims there are 11]:  
"Claims 1 to 15 replaced by amended claims 1 to 11."
3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:  
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or  
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
4. [Where various kinds of amendments are made]:  
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

### "Statement under article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

### Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the same time of filing the amendments with the International Bureau, also file a copy of such amendments with the International Preliminary Examining Authority (see Rule 62.2(a), first sentence).

### Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, where upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see Volume II of the PCT Applicant's Guide.

## PATENT COOPERATION TREATY

PCT

From the INTERNATIONAL BUREAU

NOTIFICATION CONCERNING  
SUBMISSION OR TRANSMITTAL  
OF PRIORITY DOCUMENT

(PCT Administrative Instructions, Section 411)

To:

SGARBI, Renato  
Ing. A. Giambrocono & C. s.r.l.  
Via Rosolino Pilo, 19/B  
I-20129 Milan  
ITALIE

RIC. 1 5 OTT. 1999

Date of mailing (day/month/year) 04 October 1999 (04.10.99)	IMPORTANT NOTIFICATION
Applicant's or agent's file reference RS/mg G67827	
International application No. PCT/EP99/05137	International filing date (day/month/year) 19 July 1999 (19.07.99)
International publication date (day/month/year) Not yet published	Priority date (day/month/year) 30 July 1998 (30.07.98)
Applicant BIOSEARCH ITALIA S.P.A. et al	

- The applicant is hereby notified of the date of receipt (except where the letters "NR" appear in the right-hand column) by the International Bureau of the priority document(s) relating to the earlier application(s) indicated below. Unless otherwise indicated by an asterisk appearing next to a date of receipt, or by the letters "NR", in the right-hand column, the priority document concerned was submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b).
- This updates and replaces any previously issued notification concerning submission or transmittal of priority documents.
- An asterisk(\*) appearing next to a date of receipt, in the right-hand column, denotes a priority document submitted or transmitted to the International Bureau but not in compliance with Rule 17.1(a) or (b). In such a case, the attention of the applicant is directed to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.
- The letters "NR" appearing in the right-hand column denote a priority document which was not received by the International Bureau or which the applicant did not request the receiving Office to prepare and transmit to the International Bureau, as provided by Rule 17.1(a) or (b), respectively. In such a case, the attention of the applicant is directed to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

<u>Priority date</u>	<u>Priority application No.</u>	<u>Country or regional Office or PCT receiving Office</u>	<u>Date of receipt of priority document</u>
30 July 1998 (30.07.98)	98114368.8	EP	03 Sept 1999 (03.09.99)

The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

Facsimile No. (41-22) 740.14.35

Authorized officer

Marc Salzman

Telephone No. (41-22) 338.83.38

# PATENT COOPERATION TREATY

PCT

From the INTERNATIONAL BUREAU

## NOTICE INFORMING THE APPLICANT OF THE COMMUNICATION OF THE INTERNATIONAL APPLICATION TO THE DESIGNATED OFFICES

(PCT Rule 47.1(c), first sentence)

To:

SGARBI, Renato  
Ing. A. Giambrocono & C. s.r.l.  
Via Rosolino Pilo, 19/B  
I-20129 Milan  
ITALIE

Date of mailing (day/month/year)

10 February 2000 (10.02.00)

Applicant's or agent's file reference

RS/mg G67827

### IMPORTANT NOTICE

International application No.

PCT/EP99/05137

International filing date (day/month/year)

19 July 1999 (19.07.99)

Priority date (day/month/year)

30 July 1998 (30.07.98)

Applicant

BIOSEARCH ITALIA S.P.A. et al

1. Notice is hereby given that the International Bureau has communicated, as provided in Article 20, the international application to the following designated Offices on the date indicated above as the date of mailing of this Notice:

AU,CN,EP,IL,JP,KP,KR,US

In accordance with Rule 47.1(c), third sentence, those Offices will accept the present Notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

2. The following designated Offices have waived the requirement for such a communication at this time:

AE,AL,AM,AP,AT,AZ,BA,BB,BG,BR,BY,CA,CH,CU,CZ,DE,DK,EA,EE,ES,FI,GB,GD,GE,GH,GM,HR,  
HU,ID,IN,IS,KE,KG,KZ,LC,LK,LR,LS,LT,LU,LV,MD,MG,MK,MN,MW,MX,NO,NZ,OA,PL,PT,RO,RU,  
SD,SE,SG,SI,SK,SL,TJ,TM,TR,TT,UA,UG,UZ,VN,YU,ZA,ZW

The communication will be made to those Offices only upon their request. Furthermore, those Offices do not require the applicant to furnish a copy of the international application (Rule 49.1(a-bis)).

3. Enclosed with this Notice is a copy of the international application as published by the International Bureau on 10 February 2000 (10.02.00) under No. WO 00/06119

### REMINDER REGARDING CHAPTER II (Article 31(2)(a) and Rule 54.2)

If the applicant wishes to postpone entry into the national phase until 30 months (or later in some Offices) from the priority date, a demand for international preliminary examination must be filed with the competent International Preliminary Examining Authority before the expiration of 19 months from the priority date.

It is the applicant's sole responsibility to monitor the 19-month time limit.

Note that only an applicant who is a national or resident of a PCT Contracting State which is bound by Chapter II has the right to file a demand for international preliminary examination.

### REMINDER REGARDING ENTRY INTO THE NATIONAL PHASE (Article 22 or 39(1))

If the applicant wishes to proceed with the international application in the national phase, he must, within 20 months or 30 months, or later in some Offices, perform the acts referred to therein before each designated or elected Office.

For further important information on the time limits and acts to be performed for entering the national phase, see the Annex to Form PCT/IB/301 (Notification of Receipt of Record Copy) and Volume II of the PCT Applicant's Guide.

The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

Authorized officer

J. Zahra

Facsimile No. (41-22) 740.14.35

Telephone No. (41-22) 338.83.38

TENT COOPERATION TRE Y

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Assistant Commissioner for Patents  
United States Patent and Trademark  
Office  
Box PCT  
Washington, D.C. 20231  
ÉTATS-UNIS D'AMÉRIQUE

in its capacity as elected Office

Date of mailing:

10 February 2000 (10.02.00)

International application No.:

PCT/EP99/05137

Applicant's or agent's file reference:

RS/mg G67827

International filing date:

19 July 1999 (19.07.99)

Priority date:

30 July 1998 (30.07.98)

Applicant:

PARENTI, Francesco et al

1. The designated Office is hereby notified of its election made:



in the demand filed with the International preliminary Examining Authority on:

20 December 1999 (20.12.99)



in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was



was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer:

J. Zahra

Telephone No.: (41-22) 338.83.38